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March 21, 2014

BY ECF

Honorable Colleen McMahon
United States District Judge
United States Courthouse
500 Pearl Street, Room 1350
New York, New York 10007

Re: ***U.S. ex rel. David M. Kester, et al. v. Novartis Pharmaceuticals Corporation, et al.*, Case No. 11-CIV-8196 (CM) (JCF)**

Dear Judge McMahon:

Pursuant to the Court's instructions at the initial conference in this case on March 14, 2014 and the Court's minute entry of the same date, the Intervening States write to address the issues raised by Novartis Pharmaceuticals Corporation's motion to dismiss relating to Fed. R. Civ. P. 9(b).[1] *See* ECF No. 141.

Drug companies cannot pay pharmacies to act like pharmaceutical sales reps. As Novartis' own compliance policies summarizing anti-kickback laws recognize, pharmacists are healthcare professionals, and Novartis cannot inappropriately influence a pharmacy's decision to "dispense, recommend, [or] purchase" a drug. (MS Cmplt. ¶ 46)[2] Here, Novartis used its control of Exjade prescriptions to provide patient referrals (and discounts) to BioScrip, Inc. in exchange for the pharmacy's agreement to recommend the drug to patients. The purpose of this scheme

[1] The Intervening States are: California; Georgia; Illinois; Indiana; Maryland; Michigan; New Jersey; New York; Oklahoma; Washington; and Wisconsin.

[2] "MS Cmplt." refers to the multistate Complaint In Intervention of all of the Intervening States except California and Washington. *See* ECF No. 61. For brevity, this letter cites to the multistate Complaint and not the separately-filed but nearly identical complaints of California and Washington. *See* ECF Nos. 60, 82. Although parallel cites to these two complaints are not provided here, they are substantially similar to the multistate Complaint, and the arguments and analysis in this letter apply equally to the Complaints In Intervention of California and Washington.

was to stem the tide of patients discontinuing their Exjade therapy because of side effects, and, according to Novartis' own documents, this scheme was successful in persuading patients to continue or resume therapy. This corruption of the health care system is precisely what federal and state anti-kickback laws and regulations are designed to prevent. When Medicaid providers accept kickbacks, the Intervening States do not pay for their claims. Here, Novartis provided patient referrals and discounts to BioScrip as part of a kickback scheme, and therefore the resulting claims are false and ineligible for payment for purposes of the Intervening States' False Claims Act and other laws prohibiting fraud.

Factual Background

In late 2005, Novartis launched the drug Exjade, which is used to reduce excess iron in the body that results from repeated blood transfusions. (MS Cmplt. ¶¶ 57, 41) About a year later, Novartis grew concerned that the drug would not meet internal sales targets and conducted a series of analyses to understand why. (*Id.* at ¶¶ 79, 2, 74) These analyses revealed, according to Novartis' own documents, that many Exjade patients were discontinuing the use of the drug because of side effects. (*Id.* at ¶¶ 74-75)

In some respects, the problem of patient discontinuation was created by Novartis itself. In marketing Exjade, Novartis deliberately chose to promote the drug's use among a group of patients who had fewer transfusions and therefore less medical need for the drug than traditional candidates for iron-reduction therapy. (*Id.* at ¶ 76) In early 2007, Novartis recognized that these patients, who were often elderly and frail, were more likely to choose to stop taking Exjade because of side effects. (*Id.* at ¶¶ 75-76) Indeed, by early 2010, the U.S. Food & Drug Administration determined that the risks of taking Exjade for many of these patients outweighed the benefits and required Novartis to limit the labeled uses for the drug. (*Id.* at ¶ 76) To some extent, patient discontinuation simply reflected the fact that the drug's side effects were "higher in the real world than reported in clinical trials." (*Id.* at ¶ 62) Following Exjade's launch, a series of warnings were added to Exjade's label based on this real-world experience, which culminated in a three-part "Black Box" warning for gastrointestinal bleeding, kidney failure, and liver failure. (*Id.* at ¶¶ 62-64)

Novartis' initial plan to combat patient discontinuation centered on the development of a set of "educational" materials for patients. (*Id.* at ¶ 70) However, the company had difficulty getting these materials approved by FDA. (*Id.* at ¶ 70 n.2) As an alternative, in early 2007 Novartis turned to BioScrip, Inc., one of three so-called specialty pharmacies that Novartis permitted to ship Exjade prescriptions to patients across the country. (*Id.* at ¶ 67-68)

Novartis exercised control over most Exjade prescriptions in the United States by setting up a closed distribution network or "hub" called EPASS that was run by a Novartis vendor. (*Id.* at ¶¶ 67, 72) With limited exceptions, doctors had to send their Exjade prescriptions to EPASS in order to get them filled. (*Id.* at ¶ 72) This hub would assign each prescription to one of three specialty pharmacies, who would ship the drug to patients. (*Id.* at ¶¶ 69, 72) Following the launch of Exjade, Novartis promoted this system to doctors and patients as more than just a way to get prescriptions filled. Instead, Novartis told doctors and patients that enrolling in EPASS would give patients access to clinical education and counseling from nurses and pharmacists at

the EPASS pharmacies. (*Id.* at ¶¶ 105-08) At BioScrip, call center personnel told new patients they would receive a call from a nurse about their therapy and invited the patients to call BioScrip if they experienced side effects. (*Id.* at ¶ 108)

In early 2007, Novartis leveraged its control over Exjade prescription referrals by threatening to reduce or eliminate prescription referrals to BioScrip if the pharmacy did not undertake efforts to keep patients on Exjade longer. (*Id.* at ¶¶ 79-85) In response, BioScrip agreed to provide one-sided information to patients about the benefits and risks (*i.e.* side effects) of taking Exjade as a matter of course. (*Id.* at ¶¶ 84-86) In addition to recommending that patients refill their prescriptions, BioScrip agreed to call patients who had stopped taking Exjade and encourage them to restart the drug. (*Id.* at ¶ 84) The BioScrip personnel making these calls have admitted that they had little knowledge of Exjade or the underlying conditions from which the patients suffered and that they were pressured by their supervisors to convince patients to accept shipments to meet sales targets, which were set by Novartis. (*Id.* at ¶¶ 86, 6, 101-102) In essence, BioScrip abandoned its obligation to provide objective clinical guidance to patients and instead served as a sales force for Novartis, promoting the use of Exjade to patients. (*Id.* at ¶ 100)

In the ensuing years, Novartis continued to provide a mix of incentives to BioScrip to encourage it to promote Exjade to patients to boost sales. In 2007, Novartis developed a "scorecard" that measured the length of time patients for each EPASS pharmacy stayed on Exjade. (*Id.* at ¶ 88) Novartis reviewed the scorecard with BioScrip each month, along with tactics on how to promote Exjade, and awarded extra patient referrals to the EPASS pharmacy (often BioScrip) that succeeded in keeping patients on the drug the longest. (*Id.* at ¶¶ 88, 93, 96) Novartis also continued the threat to take valuable patient referrals away from BioScrip if its scores faltered and actually did so in 2011. (*Id.* at ¶¶ 125-27) In addition, Novartis offered increased rebates and discounts to BioScrip that were designed to incentivize BioScrip to continue to recommend Exjade and "maximize[] length on therapy." (*Id.* at ¶¶ 91-104)

According to Novartis' own documents, this mix of incentives boosted Exjade sales through BioScrip. For instance, in late 2007, Novartis estimated that a BioScrip Exjade patient was "worth $800-$2,800 more" than Exjade patients serviced by other pharmacies. (*Id.* at ¶ 91) Likewise, in 2011, Novartis completed a study to determine the effect that nurses and others who promoted Exjade at BioScrip had on refill rates. That study that found BioScrip patients stayed on Exjade 9.3 days longer than patients of another pharmacy. (*Id.* at ¶ 104)

Medicaid Claims Affected by Kickbacks Give Rise to False Claims Act Liability

In each of the Intervening States, compliance with anti-kickback laws and regulations is a core condition of payment for Medicaid claims. By way of example, New York's Medicaid regulations identify several "unacceptable practices" that "consitute[] fraud or abuse" for which the program will not pay claims. 18 N.Y.C.R.R. § 515.2(b). Among these unacceptable practices are "Bribes and kickbacks" that include kickbacks provided in exchange for "referring" Medicaid recipients or "recommending any medical care" to recipients. *Id.* at § 515.2(5). In *New York v. Amgen,* the First Circuit reviewed this regulatory framework and concluded that claims submitted to New York's Medicaid program are "not entitled to Medicaid payment if they

are affected by kickbacks. . . ." *New York v. Amgen Inc.*, 652 F.3d 103, 111-14 (1st Cir. 2011). Similarly, claims affected by kickbacks are ineligible for payment by the Medicaid programs of the Intervening States. (MS Cmplt. ¶ 29)

Because the Intervening States do not pay for claims affected by kickbacks, such claims to the Intervening States' Medicaid programs constitute false or fraudulent claims for purposes of their False Claims Acts. In this circuit, such claims are sometimes referred to as legally false claims that give rise to liability under the federal False Claims Act and similar state statutes. *See Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001).[3]

BioScrip's Claims for Exjade During the Period it Accepted Kickbacks are False

As described above, Novartis gave patient referrals, discounts, and rebates to BioScrip during the period from February 2007 to May 2012. In exchange, BioScrip hired nurses and call center personnel and agreed to have them recommend Exjade to patients by providing one-sided information about the drug. This agreement to *refer* patients and *recommend* Exjade violated the Intervening States' prohibitions on kickbacks as well as the federal Anti-Kickback Statute. *See, e.g.* 18 N.Y.C.R.R. § 515.2; 42 U.S.C. § 1320a-7b(b).

Under this scheme, the Exjade patient referrals served as both the inducement and reward to BioScrip for its agreement to recommend Exjade to patients. Therefore, all of the Medicaid claims submitted by BioScrip resulting from these referrals were false claims.

The Intervening States' complaints also allege that Novartis provided additional kickbacks in the form of discounts and rebates to BioScrip starting in early 2008 to induce it to continue to recommend Exjade to patients. (MS Cmplt. ¶¶ 95, 97, 103) One of these rebates (the "Performance Rebate") was based upon the total volume of Exjade sales made by BioScrip, was part of a scheme that was not properly disclosed, and applied to virtually all of BioScrip's Exjade purchases. (MS Cmplt. ¶ 95) Therefore, all of the Exjade claims that BioScrip submitted to the Intervening States' Medicaid programs after these rebates were put in place were the result of these kickbacks.

In its motion to dismiss, Novartis alleges that a 2010 amendment to the federal Anti-Kickback Statute imposed additional limitations on federal False Claims Act liability in kickback cases. (ECF No. 141 at 7, citing 42 U.S.C. § 1320a-7b(g)) Neither the text of the amendment nor the legislative history provide any support for Novartis' interpretation. As at least one court makes clear, the amendment "evinces Congress' intent to clarify, not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the FCA." *See U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp.2d 39, 52-53 (D. Mass. 2011). In any event, Novartis' argument has no merit because the Intervening States have properly plead that all of BioScrip's Exjade claims during the period it received kickbacks were the result of those kickbacks.

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[3] The Intervening States have properly plead additional theories of liability, such as the submission of false certifications that failed to disclose the kickbacks identified in the complaint. (MS Cmplt. ¶¶ 39, 296)

The Intervening States' complaints in this case reflect the well-established principle that federal and state health care programs do not pay for claims tainted by kickbacks, regardless of whether the services were provided. In *United States v. Rogan*, for instance, the Seventh Circuit upheld a treble damage award that included all of the claimed services because they were result of improper referrals. 517 F.3d 449, 453 (7th Cir. 2008). In doing so, the court rejected the defendant's argument that the claimed services were provided as irrelevant, along with the contention that the patients would have received similar treatment elsewhere. *Id*. This ruling is consistent with the False Claims Act's legislative history that indicates a claim "'may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program. . . .'" *U.S. ex rel. Antidiscrimination Center of Metro New York, Inc. v. Westchester County*, No. 06-2860, 2009 WL 1108517, at *2 (April 24, 2009 S.D.N.Y.) (quoting S. Rep. No. 99-345 at 9, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5275). *See also U.S. ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011) (denying motion to dismiss where plaintiff alleged that doctors received kickbacks to use certain products in surgeries that actually occurred); *U.S. ex rel. McNutt v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005) (denying motion to dismiss where kickbacks to pharmacists in exchange for referrals rendered claims ineligible for payment); *U.S. ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp.2d 112, 129 (D. Mass. 2011) (denying motion to dismiss in pharmacy kickback case where government alleged that all claims for multiple drugs were false and complaint cited pharmaceutical company documents "boasting" about the pharmacy's success in moving market share).

The Intervening States' Complaints Satisfy Fed. R. Civ. P. 9(b)

The Intervening States have given Novartis ample notice of the claims against it under Fed. R. Civ. P. 9(b). As it must, Novartis does not dispute that the Intervening States' complaints properly plead that Novartis paid kickbacks to BioScrip to promote Exjade. Instead, Novartis relies on cases where relators did not identify any false claims, even though the Intervening States' complaint have done much more. These complaints specify the time period in which the false claims were submitted, the pharmacy that submitted the false claims for Exjade, the number of false claims, and the amounts paid by each state for those claims. (MS Cmplt. ¶¶ 43-44, 133) This is more than sufficient to meet the Intervening States' burden of pleading "'reliable indicia that lead to a strong inference that claims were actually submitted.'" *Parikh v. Citizens Medical Ctr.*, No. 10-64, 2013 WL 5304057, at *7 (S.D. Tex. Sept. 20, 2013) (quoting *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); *see also U.S. ex rel. Associates Against Outlier Fraud v. Huron Consulting Group, Inc.*, No. 09-1800, 2011 WL 253259, at *2 (S.D.N.Y. Jan. 24, 2011) (applying the standard in *Grubbs*).

Further, in this case, Novartis actually has even more detailed information about the claims BioScrip submitted for Exjade during the period it received kickbacks: as an EPASS pharmacy, BioScrip provided detailed information to the hub about each Exjade prescription, including the insurer, date, doctor, and underlying condition of the patient. Accordingly, there is no need for the Intervening States to provide sample claims in this case. *See U.S. ex rel. Strom v. Scios, Inc.*, 676 F. Supp.2d 884, 893-94 (N.D. Cal. 2009) (identifying "the specifics" of an "immense number of claims" is unnecessary because defendant was on notice of the conduct at

issue even though there may be disputes as to "which claims" were caused by the fraudulent activity); *U.S. ex rel. Singh v. Bradford Reg'l Medical Ctr.*, No. 04-186, 2006 WL 2642518, at *7 (W.D. Pa. Sept. 13, 2006) (relator not required to provide claim examples). Accordingly, Novartis' motion to dismiss should be denied, and this case should proceed.

We thank the Court for its consideration of this letter. Pursuant to the Court's minute entry of March 14, 2014, we have only addressed the issues in Novartis' motion to dismiss relating to Fed. R. Civ. P. 9(b). As the Court is aware, Novartis' motion also addresses other issues concerning the Intervening States' claims, such as the retroactivity of certain states' False Claims Acts. We are prepared to address these issues in a brief on March 28, 2014, as originally scheduled, or at any other time thereafter that is convenient for the Court.

Respectfully submitted,

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